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EQUITY RESEARCH
Company Report

May 7, 2015

Repros Therapeutics (RPRX - $ 7.46)

Healthcare/Biotechnology

1Q15: Uneventful Quarter with Androxal in Secondary Hypogonadism AdCom Meeting and PDUFA Decision the Key Focus in 2015.

Ticker:	**RPRX**
Rating:	**Buy**
Price Target:	**$ 28.00**

This morning, RPRX reported 1Q15 financial results with a net loss of ($8.5MM) or ($0.35) /share. The company ended 1Q15 with ~$38MM cash, enough to support its operations deep into 2016, in our opinion.

- **Androxal AdCom meeting and PDUFA preparations are in high gear**. RPRX recently announced that the PDUFA date for Androxal in secondary hypogonadism potential approval is scheduled on November 30, 2015. Given Androxal is a new chemical entity (NCE) and with very different mechanism of action vs. all other current therapies in treating secondary hypogonadism; an AdCom meeting is very likely to be held for the FDA to present their own, and seek outside expert, opinions. Our discussion with management indicated that the company is in high gear for preparation of the anticipated AdCom meeting. We estimate the meeting could be held in the September/October timeframe. Near term, RPRX will provide multiple presentations (see schedule on following pages) at the May 15 -19 American Urological Association (AUA) annual meeting. These include a plenary oral presentation by Drs. Andrew McCullough and Edward Kim. With the robust results of multiple Phase III studies, we remain bullish on a positive outlook from the AdCom meeting and likely approval by the FDA for Androxal.
- **Proellex in uterine fibroids (UF) clinical studies underway.** Two Phase IIb studies (each with different delivery methods: oral and vaginal) evaluating Proellex in UF are ongoing. Should patient recruitment proceeds as expected, RPRX would report the interim results (from patients completed one of the two treatment cycles) in late 4Q15. The company also plans to conduct a Type C meeting with the FDA (possibly by year-end 2015 or early 2016). The objective of the meeting is to discuss the possible patient size for the safety database required for the potential NDA filing, once the company completes a subsequent Phase III study and with positive outcomes.
- **Action.** We are reiterating our Buy rating, and our target price of $28 to reflect our positive outlook for Androxal and clinical advancement of Proellex. Our valuation is based on our P/E, NPV-driven-and-probability adjusted sum-of-the-parts analyses.

Trading Data:

Last Price (05/07/2015)	$ 7.46
52–Week High (9/2/2014)	$ 22.55
52–Week Low (10/21/2014)	$ 5.92
Market Cap. (MM)	$ 181
Shares Out. (MM)	24

Earnings Estimates: (per share)

(Dec)	1Q	2Q	3Q	4Q	FY	P/E
FY-15E	-0.35A	-0.20	-0.20	-0.20	-0.96	NM
FY-14A	-0.37	-0.38	-0.32	-0.31	-1.37	NM
FY-13A	-0.41	-0.38	-0.26	-0.31	-1.33	NM
FY-12A	-0.17	-0.21	-0.30	-0.47	-1.18	NM

Source: Laidlaw & Company estimates

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Schedule of Androxal relevant presentations at the AUA meetings

Friday, May 15, 2015 10:30 AM-12:30 PM; NOMCC: Prostate Cancer: Epidemiology & Natural History I.

> **MP4-09: Endogenous and exogenous testosterone and the risk of prostate cancer and prostate specific antigen** *Peter Boyle*, Alice Koechlin, Maria Bota, Ecully, France, Alberto d'Onofrio, Lyon, France, David G Zaridze, Moscow, Russian Federation, Paul Perrin, Lyon, France, John Fitzpatrick, Dublin, Ireland, Arthur L Burnett, Baltimore, MD, Mathieu Boniol, Ecully, Fr*

Saturday, May 16th 2015. 12.05 -1.05 pm. SMSNA Annual Meeting, "CHERCHEZ LA FEMME"ESTROGENS AND THEIR ROLE IN MALE GONADAL FUNCTION. Program Chairman: Andrew McCullough, MD

> **Estrogens and their receptors in the male: Brains, bones, and balls.** *Stephen Winters, MD*
>
> **The aging male pituitary gonadal axis: Planned obsolescence.** *Johannes Veldhuis, MD*
>
> **The use of SERMS in the treatment of male secondary hypogonadism: When the factories can still put out.** *Wayne Hellstrom, MD*

Saturday, May 16th. 05:45 p.m. - 05:55 p.m. SMSNA, SESSION 12 -THE PIPELINE: DRUG DEVELOPMENT IN SEXUAL HEALTH

> **Phase III studies, show Endroxal™ (enclomiphene citrate) sig-nificantly improves total testosterone compared to Androgel 1.62%, without suppression of spermatogenesis and testicular atrophy in overweight men with secondary hypogonadism.** *Andrew R. McCullough, MD*

Sunday, May 17, 2015 10:45 AM-11:41 AM, Plenary II - Sunday (Oral presentation)

> **PII-LBA7: In two phase III studies, EndroxalTM (enclomiphene citrate) significantly improves total testosterone levels compared to Androgel 1.62%, without suppression of spermatogenesis and testicular function in overweight males with secondary hypogonadism.** *Andrew McCullough*, Albany, NY, Edward Kim, Knoxville, TN, Michael Wyllie, Banbury, United Kingdom*

Sunday, May 17th 2015 12.00- 1.00pm, Society for the Study of Male Reproduction, Clomiphene a New twist

> **12.00-12.05 Introduction.** *Ed Kim.*
>
> **12.05-12.20. Clomiphene and its use in infertile men,** *Wayne Hellstorm*
>
> **12.20-12.40. Enclomiphne: effect on hormonal profiles and metabolic parameters.** *Andy McCullough.*
>
> **12.40-12.55. Safety and sperm studies** *Ed Kim*

Monday, May 18 1.00 -3.00pm: AUA Town Hall. Testosterone: Too much or not enough? Moderator-Gregory A. Broderick, MD, Moderator-Ajay K. Nangia, MD, Moderator-Ridwan Shabsigh, MD

> **1 p.m.-1:12 p.m. Testosterone is Being Overprescribed and T Advertising is Inappropriate**
>
> **Panelist - Disagree:** *Martin M. Miner, MD***; Panelist - Agree:** *Mark Sigman, MD*

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1:12 p.m.-1:24 p.m. Age Discrimination or Age Specific Precautions: Will New Guidelines from the FDA Protect Elderly Male Patients or Condemn Them to Live with the Symptoms of Hypogonadism

Panelist - Protect: *Glenn R. Cunningham, MD* **Panelist - Condemn:** *Adrian Dobs, MD*

1:24 p.m.-1:36 p.m. Testosterone Increases Cardiovascular Morbidity

Panelist - Agree: Shehzad Basaria, MD; Panelist - Disagree: Mario Maggi, MD

1:36 p.m.-1:40 p.m. Panel Wrap-Up

ANDROGEN THERAPEUTICS: ARE YOU AN EXPERT PROVIDER? Moderator: *Gregory A. Broderick, MD*

1:40 p.m.-1:47 p.m. Therapeutic Options and Best Practices in Management; Speaker: *John P. Mulhall, MD*

1:47 p.m.-1:54 p.m. Erythrocytosis Could This be the Key to Cardiovascular Risk. Speaker: *Wayne J.G. Hellstrom, MD*

1:54 p.m.-2:14 p.m. Anabolic Steroids, a Candid Conversation Between Patient and Physician. Speaker: *Tobias S. Kohler, MD, MPH;* **Speaker:** *Chad Schaive*

2:14 p.m.-2:20 p.m. Wrap-up

2:20 p.m.-3 p.m. Androgen Town Hall: Expert Answers for the Urologic Community. Moderator: *Ridwan Shabsigh, MD***, Panelist:** *Arthur L. Burnett, II, MD, Mark S. Hirsch, MD, Mohit Khera, MD, MBA, MPH, Mario Maggi, MD and John P. Mulhall, MD.*

Monday May 18th 2015 3.30 to 4.30pm. AUA Press Conference. Peter Boyle Endogenous and exogenous testosterone and the risk of prostate cancer and prostate specific antigen

- **Long-term Treatment with Testosterone Undecanoate Injections Sustainably Improves Erectile Dysfunction and Metabolic Control in Hypogonadal Men with Type 2 Diabetes Mellitus (T2DM)**
- **Effects of Continuous Long-term Testosterone Replacement Ther-apy (TRT) up to 11 Years in 115 Hypogonadal Elderly Men on Anthropometric, Endocrine and Metabolic Parameters: real-life Experience from an Observational Registry Study**
- **Association Between Testosterone and Thrombotic Events in Elderly Men**

Source: 2015 AUA annual meeting

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Anticipated milestones in 2015 and beyond

Program	Indication	Event	Timing	Importance
Androxal	Secondary hypogonadism	FDA expert panel meeting	**2H15**	*****
		Clinical data presentation at AUA	**May 15 -19, 2015**	***
		Expected PDUFA date	**Nov. 30, 2015**	*****
		Potential partnership or other business development activities	**2015 / 2016**	*****
		Potential approval for 2nd hypogonadism	**4Q15 / 1Q16**	*****
Proellex	Uterine Fibroids	Potentially to report top-line results after one cycle treatment from low dose Proellex Phase II study	**4Q15**	****
		Potentially to schedule a type C meeting with the FDA to discuss Proellex Phase III study	**Late 15 / early 16**	****
		Potentially to determine low dose oral vs. vaginal Proellex as final format for Phase III trial	**2H15**	****
		Potentially to start a Phase III study	**2016**	*****
	Endometriosis	Possible to complete patient enrollment for Phase II study	**2015**	***
		Possible to report Phase II study top-line results	**1Q16**	***

***** / ***** Major catalyst event that could impact share price very significantly while *** event is more informative*

Source: Laidlaw & Company estimates and company presentation.

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Major risks

Clinical risks of trial study failure could have a significantly negative impact on RPRX share value. Given that Androxal in secondary hypogonadism is the most advanced and most promising program in Repros' product portfolio, we believe the majority of RPRX share value (assessed by both us and the Street) resides in the potential clinical and regulatory success of this program. Even with a lower probability of clinical failure, in our opinion, a scenario where the FDA requests significantly more difficult Phase III studies at the upcoming meeting, should the company be unable to accomplish such a task; could significantly reduce RPRX share value. As such, we view the outcome from the FDA discussion and report of the top-line results from the pivotal comparative trials (possibly in 4Q14) could be important binary events for RPRX shares.

Market potential of Androxal in secondary hypogonadism is lower than projected. With well-differentiated attributes, such as retaining spermatogenesis compared to marketed testosterone replacement products, coupled with the trend of increased prescription, and substantial unmet medical need; we believe the commercial outlook of Androxal could be substantial. However, given Androxal is a non-testosterone and competes in an environment of a well-entrenched TRT treatment paradigm, substantial and effective education efforts, in our opinion, are necessary to change physicians' prescribing habits and expand Androxal sales. The potential patent expiration of AndroGel could be an opportunity for Androxal but it also could become a challenge that limits Androxal's pricing flexibility. Overall, if our projection for the future market dynamics is incorrect, or the execution by the company (given the current management team has limited product commercialization experience), or potential licensing partner is inadequate; the revenue outlook for Androxal could disappoint.

Androxal patent dispute could potentially affect the economics RPRX receives. The company is currently in a legal dispute with Dr. Harry Fisch, who claims the two patents encompassing clomid as a treatment for hypogonadism. Despite the fact that the U.S. Patent and Trademark Office (PTO) recently reversed the rejections of Dr. Fisch's patent infringement claims, it might be too early or too uncertain, in our opinion, to determine the ultimate resolution. If such patents are not invalidated by the PTO or a court of competent jurisdiction, the company may be required to obtain a license, potentially for a fee, from the holder of such patents in order to develop Androxal further. Although we do not anticipate such a scenario would derail the development or commercial outlook of Androxal, we believe the economic reward to the company would be reduced modestly.

Although promising, low dose Proellex and Proellex-V must still demonstrate proof-of-concept results. Although the current clinical data

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regarding efficacy and safety from the low-dose oral Proellex and newly-developed Proellex-V study are encouraging, it is still be too early to fully project the product's future in endometriosis and in uterine fibroids. In addition, it is still uncertain as which format of Proellex would be used for UF development going forward. Further, low dose oral Proellex in endometriosis Phase II study is still ongoing and we believe a positive efficacy and satisfactory safety profile are needed from the study to potentially to fully lift the clinical hold by the FDA to advance the program. Any negative outcomes could also a setback although Proellex only accounts for a minor portion of the RPRX valuation.

Potential financing could dilute shareholders. Although we estimate that the company's cash position could support operations, including R&D and M&S expenses, into 2016; the possibility exists that additional cash could be needed for other unexpected corporate development activities. If not from the non-dilutive sources, options could include a potentially-dilutive equity offering, of which could potentially affect current shareholders negatively due to dilution. However, we view such risk could be offset by the substantial value increase of the company's assets due to clinical advancement leading to commercialization.

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Figure 1: Income Statement

Repros Therapeutics – Income Statement

($ MM)	2013	2014	1Q15	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E
Revenue										
Licensing fees	-	-	-	-	-	-	-	10.0	10.0	10.0
Product revenue	-	-	-	-	-	-	-	0.0	65.7	115.9
Research and development grants	-	-	-	-	-	-	-	-	-	-
Interest income	0.0	0.0	-	-	-	-	-	-	-	-
Gain on disposal of fixed assets	0.0	-	-	-	-	-	-	-	-	-
Other Income	-	-	-	-	-	-	-	-	-	-
Total Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$10.0	$75.7	$125.9
Costs of goods								0.0	6.6	11.6
Gross revenue								10.0	69.2	114.3
Research and development	22.9	26.7	7.3	3.7	3.8	3.9	18.8	19.3	21.3	23.2
General and administrative	4.8	5.4	1.2	1.2	1.2	1.2	4.8	7.2	8.0	8.0
Sales and marketing		0.0	-	-	-	-	0.0	14.0	16.1	18.5
Interest expense and amortization of intangibles	-	-	-	-	-	-	0.0	-	-	-
Total Operating Expenses	$27.7	$32.1	$8.5	$4.9	$5.1	$5.1	$23.6	$40.6	$29.2	$31.2
Operating Income (loss)	($27.7)	($32.1)	($8.5)	($4.9)	($5.0)	($5.1)	($23.6)	($30.6)	$39.9	$83.1
Loss from continuing operations	-	-	-	-	-	-	-	-	-	-
Gain on disposal of discontinued operation	-	-	-	-	-	-	-	-	-	-
Net loss before cumulative effect of change in accounting principle	(27.7)	(32.1)	(8.5)	(4.9)	(5.0)	(5.1)	(23.6)	(30.6)	39.9	83.1
Cumulative effect of change in accounting principle	-	-	-	-	-	-	-	-	-	-
Income (loss) before tax expense	(27.7)	(32.1)	(8.5)	(4.9)	(5.0)	(5.1)	(23.6)	(30.6)	39.9	83.1
Income tax expense	-	-	-	-	-	-	-	0.0	13.6	28.3
Net Incomes (Losses)	($27.7)	($32.1)	($8.5)	($4.9)	($5.0)	($5.1)	($23.6)	($30.6)	$26.3	$54.8
Net Earnings (Losses) Per Share—Basic	($1.33)	($1.37)	($0.35)	($0.20)	($0.20)	($0.20)	($0.96)	($1.22)	$1.04	$2.13
Net Earnings (Losses) Per Share—Diluted	($1.33)	($1.37)	($0.35)	($0.20)	($0.20)	($0.20)	($0.96)	($1.22)	$1.04	$2.13
Shares outstanding—basic	20.8	23.4	24.3	24.5	24.7	24.9	24.6	25.0	25.4	25.8
Shares outstanding—diluted	20.8	23.4	24.3	24.5	24.7	24.9	24.6	25.0	25.4	25.8
Margin Analysis (% of Revenue)										
COGS		N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	10%	10%	10%
R&D	254578%	888433%	732100%	186686%	192286%	194209%	N.A.	193%	28%	18%
SG&A	53533%	181233%	120500%	59648%	60244%	60846%	N.A.	72%	11%	6%
Operating Income (loss)	-308011%	-1069567%	-852500%	-246233%	-252430%	-254955%	N.A.	-306%	53%	66%
Pretax	0%	-1069567%	-852500%	-246233%	-252430%	-254955%	N.A.	0%	0%	0%
Tax Rate	0%	0%	0%	0%	0%	0%	0%	0%	34%	34%
Net Income	-308011%	-1069567%	-852500%	-246233%	-252430%	-254955%	N.A.	-306%	35%	44%
Financial Indicator Growth Analysis (Y/Y)										
Licensing fees	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	0%	0%
Product royalties	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	76%
Research and development grants	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	0%	0%	0%
Interest income	167%	-63%	N.A.	N.A.	N.A.	-100%	-100%	0%	0%	0%
Total Revenue	200%	-67%	-50%	N.A.	N.A.	-33%	-100%	N.A.	657%	66%
Research and development	72%	16%	0%	-50%	-37%	-33%	-30%	3%	10%	9%
General and administrative	0%	13%	-2%	-5%	-6%	-27%	-11%	50%	10%	1%
Sales and marketing		N.A.					N.A.	393%	15%	15%
Operating incomes	53%	16%	0%	-43%	-32%	-32%	-26%	30%	-231%	108%
Total Other Income, net	53%	16%	0%	-43%	-32%	-32%	-26%	30%	-231%	108%
Pretax Income	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.	N.A.
Net Income	53%	16%	0%	-43%	-32%	-32%	-26%	30%	-186%	108%
EPS - Basic	13%	3%	-5%	-47%	-35%	-33%	-30%	27%	-185%	105%
EPS - Diluted	13%	3%	-5%	-47%	-35%	-33%	-30%	27%	-185%	105%
Shares outstanding—basic	36%	13%	5%	6%	6%	3%	5%	2%	2%	2%
Shares outstanding—diluted	36%	13%	5%	6%	6%	3%	5%	2%	2%	2%

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Source: Bloomberg LP; Company reports; Laidlaw & Company estimates.

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Additional information available upon request.

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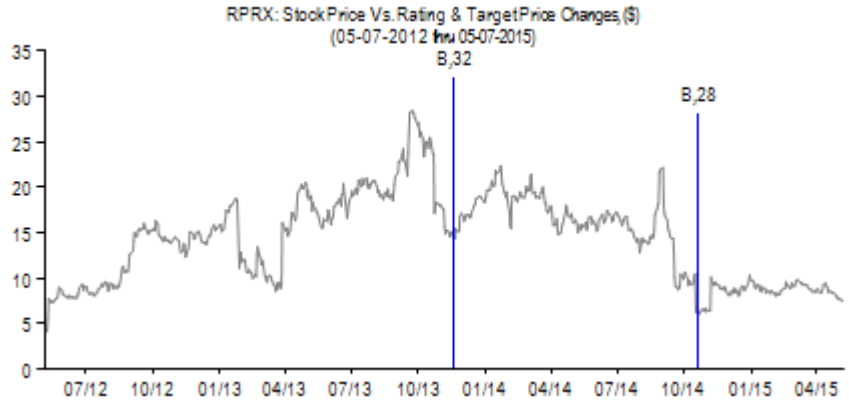
Rating and Price Target Change History



3 Year Rating Change History

Date	Rating	Closing Price ($)
11/19/2013	Buy (B)	14.59

3 Year Price Change History

Date	Target Price ($)	Closing Price, ($)
11/19/2013	32.00	14.59
10/20/2014	28.00	6.23

Source: Laidlaw & Company **Created by: Blue-Compass.net**

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			Investment Banking	Brokerage
Strong Buy (SB)	Expected to significantly outperform the sector over 12 months.	0.00%	0.00%	0.00%
Buy (B)	Expected to outperform the sector average over 12 months.	72.00%	32.00%	8.00%
Hold (H)	Expected returns to be in line with the sector average over 12 months.	4.00%	0.00%	0.00%
Sell (S)	Returns expected to significantly underperform the sector average over 12 months.	0.00%	0.00%	0.00%

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